SECURE-T2D

CLINICAL TRIAL SUMMARY

Presenters	Insulet Corporation
Objectives	To evaluate the safety and efficacy of the Omnipod 5 Automated Insulin Delivery System in adults with type 2 diabetes requiring insulin therapy.

Source: https://clinicaltrials.gov/study/NCT05815342

TRIAL DESIGN

Single-arm, Prospective, Noninferiority, followed by Superiority trial

SAMPLE SIZE

289 patients completing the 13-week follow-up period

INCLUSION CRITERIA

- Age at time of consent 18-75 years
- Diagnosed with type 2 diabetes, on current insulin regimen for at least 3 months prior to screening
- Stable doses over the preceding 4 weeks of other glucose-lowering medications as determined by Investigator
- Stable doses of weight loss medications over the preceding 4 weeks and throughout the study
- Participant agrees to provide their own insulin for the duration of the study
- Basal bolus (long-acting insulin and rapid acting analog) or pre-mix users with A1C <12.0%
- Willing to wear the system continuously throughout the study

METHODOLOGY

- 343 individuals were enrolled and 305 initiated AID, with 289 completing the 13-week follow-up period
- The primary outcome was the change in HbA1c at 13 weeks from baseline, tested sequentially for noninferiority (limit 0.3%) and superiority.
- Secondary glycemic outcomes were change from baseline in mean sensor glucose; percentage of time with sensor glucose in ranges of interest, Type 2 Diabetes Distress Assessment System (T2-DDAS), Pittsburgh Sleep Quality Index (PSQI), and Hypoglycemia Confidence Scale (HCS) total scores; proportion with high distress, poor sleep quality, and low hypoglycemia confidence, AND percentage of time with glucose less than 70 mg/dL (superiority).

RESULTS

At baseline, 73% were using multiple daily injections, 21% basal insulin without bolus, 6% an insulin pump, 62% continuous glucose monitoring, 55% glucagon-like peptide-1 receptor agonists (GLP-1RAs), and 44% were using sodium-glucose transport protein 2 inhibitors (SGLT-2is).

Following AID use, HbA1c levels decreased from a mean of 8.2% at baseline to 7.4% at 13 weeks. Improvement was seen across various subgroups (age, sex, race and ethnicity, insurance), and notably with or without use of GLP-1RAs or SGLT-2is and regardless of pretrial mealtime insulin regimen.

Time in target glucose range (70-180 mg/dL) increased from a mean of 45% to 66%. Percentage of time in hypoglycemic ranges of <54 mg/dL and <70 mg/dL was non-inferior compared with standard therapy. There was a single episode of severe hypoglycemia and none of diabetic ketoacidosis or hyperosmolar hyperglycemic syndrome.

CONCLUSION

The study reported an improvement in the glycemia over 13 weeks of using automated insulin delivery without any increase in hypoglycemia. HbA1c levels were Improved in patients using multiple daily injections and in those only on basal insulin at baseline, in diverse ethnic, racial, and socioeconomic backgrounds, and in patients using glucose lowering medications.